July 6, 2000

T A N N I N G
R E S E A R C H
LABORATORIES, INC.

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Dockets Management Branch(HFA-305)
Food and Drug Administration
5630 Fishers Lane , rm. 1061
Rockville, MD 20857

**Dear Sir/Madam:**

This letter purpose is to address the final sunscreen monograph timing needs. Despite the good intentions of the agency, the time to comply has been drastically reduced, not increased. Now industry will be officially informed of the final requirements with only one year prior to implementation. Both the date of the final monograph release, December 31, 2001, and the December 31, 2002 effective date are in the middle of the manufacturing and shipping season.

The typical new product introduction cycle for a Suncare product is quite long. Also, the seasonal nature of the product line creates other problems unique to the industry. To introduce a new product in the 2002 Suncare season, the following is a typical cycle:

1) R&D would need to begin formulation work no later than September of 2000.
2) The product would need to be formulated and most stability, SPF, and safety testing completed by June of 2001. This is the time sales presentations are made for the following season(2002).
3) Product manufacture would usually begin in late summer of 2001 with shipments starting in

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November 2001. Product not shipped by approximately May of 2002 would probably be held to the following season(2003). Leftover inventory and good merchandise returned by the retailers(most retailers do not keep the seasonal merchandise in the stores or warehouses, but return to the manufacturers after the season is over) usually amounts to 25 to 50% of the annual product made. This is a critical aspect that will either create substantial consumer confusion by having non-compliant and compliant merchandise on the same store shelves or a significant economic burden to the industry if functionally correct merchandise must be destroyed to meet retailer expectations. The US Suncare market is approximately $600,000,000 to the retailer and growing rapidly(up 9% in 2000). The present monograph timing will conservatively obsolete 25% of the inventory, or probably by 2002, $175,000,000($700,000,000 x 25%). The total manufacturer cost for this merchandise would be minimally 75% or $130,000,000. This does not include the associated costs of reformulations, testing, label development, etc.

Keeping this in mind it is easy to see that a manufacturer needs to have most of the merchandise to be sold in the 2003 season to be "phased-in" in the 2002 season. This will require a firm direction by around September of 2000. However, this is the time that comments are to be received with final requirements not to be published until December 2001. This is not enough time to formulate, perform safety and efficacy tests, produce art work, manufacture, distribute, etc. The financial burden will be incredible. Actually fulfilling the requirement may be impossible. We, Tanning Research Laboratories, were in the process of changing art to meet the new labeling requirements, but now are unsure if these efforts should be continued with another change looming.

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Based on this industry relevant timing, TRLI recommends the decision making be moved forward, or the implementation date be delayed.

Separately TRLI is considering other comments concerning information requested by the FDA.

Sincerely,

Dennis L. Lott
Executive Director of Technical Affairs

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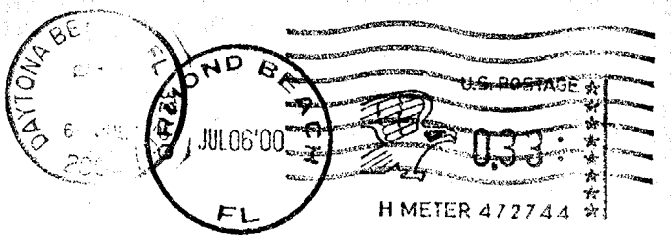


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